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Ivor R. Elrifi  
Mintz, Levin, Cohn, Ferris,  
Glovsky and Popeo, P.C.  
One Financial Center  
Boston, MA 02111

EXAMINER

SOUAYA, JEHANNE E

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/774,434

Applicant(s)

TANG ET AL.

Examiner

Jehanne Souaya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, drawn to polynucleotides and vectors and host cells comprising polynucleotides, classified in class 536, subclass 23.1, class 435, subclass 320.1, and class 435, subclasses 243 or 325, respectively.
  - II. Claims 9-10 and 19, drawn to polypeptides, classified in class 530, subclass 350.
  - III. Claim 11, drawn to antibodies, classified in class 424, subclass 130.1.
  - IV. Claims 12-14, drawn to methods of detecting polynucleotides, classified in class 435, subclass 6.
  - V. Claims 15-17, drawn to methods of detecting polypeptides, classified in class 435, subclass 7.1.
  - VI. Claim 18, drawn to a method of producing a polypeptide comprising culturing the host cell comprising a polynucleotide sequence encoding the polypeptide under conditions sufficient to express the polypeptide in the cell and isolating the polypeptide, classified in class 435, subclass 71.1.
  - VII. Claim 20, drawn to a polypeptide array, classified in class 435, subclass 174.
  - VIII. Claims 21-25, drawn to nucleic acid arrays, classified in class 435, subclass 287.2.

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IX. Claims 26 and 27, drawn to methods of treating, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I, II, and III are patentably distinct from each other because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of group III is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of groups I-III can be used in materially different processes, for example the DNA of group I can be used in hybridization assays, the antibody of group III can be used in immunoassays, and the polypeptide of group II can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, II, and III are patentably distinct from each other.

The inventions of groups I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I can be used to express proteins which is not required for the method of group IV.

The invention of group I is not related to the inventions of V, VII, and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of claim 1 is not used in the methods of groups V and IX or the polypeptide array of group VII.

The inventions of group I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group I can be used to make probes and primers for detection and amplification purposes.

The inventions of groups I and VIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because 1) the utility of a polynucleotide array does not necessarily depend on the utility of each separate polynucleotide in the array, and 2) the polynucleotide array of Group II can be

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used in a method to identify differential expression of many different genes. The subcombination has separate utility such as the distinct polynucleotides of Group I can be used in recombinant methods to express proteins.

The invention of group II is unrelated to the inventions of groups IV and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group II is not used in the method of detecting a polynucleotide of group IV or the polynucleotide array of group VIII.

The inventions of groups II and V & IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group II can be used to make fusion proteins with enzymatic functions which are not required for the method of detection of group V or the methods of treatment of group IX.

The inventions of groups II and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

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instant case the polypeptide of group II can be made synthetically and does not have to be made using the process of group VI.

The inventions of groups II and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because 1) the utility of a polypeptide array does not necessarily depend on the utility of each separate polypeptide in the array, and 2) the polypeptide array of group VII can be used in a method to identify differential expression of many different proteins. The subcombination has separate utility such as the distinct polypeptides of group II can be used to make fusion proteins with enzymatic functions.

The invention of group III is unrelated to the inventions of groups IV, VI, VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of group II are not used in the method of detecting a polynucleotide of group IV, the method of producing a polypeptide of group VI, or the polynucleotide array of group VIII. The antibodies of group II can be used in immunoassays while the polypeptide array of group VII can be synthesized chemically, without

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the use of antibodies, thus groups II and VII have different modes of operation, different functions, and different effects.

The inventions of groups III and V & IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of group III can be used in immunoassays which are not required for the method of detection of group V (the compound that binds to the polypeptide can be a specific ligand for the polypeptide) or the methods of treatment of group IX.

The inventions of groups IV, V, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of detecting polynucleotides of group IV, the method of detecting polypeptides of group V, and the methods of treatment of group IX have different modes of operation, different functions, and different effects. Each method requires different reagents, reaction conditions, and reaction parameters. Further, the inventions of groups IV, V, and IX are unobvious over one another.

The inventions of groups IV and VI are patentably distinct from each other. The method of detecting polynucleotides of group IV requires different reagents, reaction parameters, and



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reaction conditions than the method of producing the polypeptide of group VI. Further, the method of detection of group IV does not require the method of producing the polypeptide of group VI and these methods are unobvious over one another.

The inventions of groups IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of detecting a polynucleotide does not require the polypeptide array of group VII, these inventions are not capable of use together and have different modes of operation, different functions and different effects.

The inventions of groups IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of detecting a polynucleotide of group IV can be carried out without the polynucleotide array of group VIII, for example a ligand that binds specifically to the polynucleotide can be used in the method of group IV. Furthermore, the polynucleotide array of group VIII can be used to identify the differential expression of many different genes.

The inventions of groups V and VI are patentably distinct from each other. The method of detecting polypeptides of group V requires different reagents, reaction parameters, and

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reaction conditions than the method of producing the polypeptide of group VI. Further, the method of detection of group V does not require the method of producing the polypeptide of group VI and these methods are unobvious over one another.

The inventions of groups V and VII are patentably distinct from each other. The method of group V can be carried out with a specific ligand or antibody that binds to the polypeptide, and does not require the polypeptide array of group VII, while the polypeptide array of group VII can be used to identify the differential expression of many different proteins. The method of group V can be carried out with different reagents, reaction conditions, and reaction parameters from the polypeptide array of group VII.

The inventions of groups V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of detecting the polypeptide does not require the polynucleotide array of group VIII, these inventions are not capable of use together and have different modes of operation, different functions, and different effects.

The invention of group VI is patentably distinct from the inventions of groups VII and IX as the polypeptide array of group VII and the method of treating of group IX do not require the method of producing the polypeptide of group VI, the polypeptide can be produced synthetically. Furthermore, the reagents, reaction parameters, and reaction conditions to practice each invention are different.

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The inventions of groups VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of producing the polypeptide of group VI has different modes of operation, different functions, different effects and is not required for the polynucleotide array of group VIII.

The inventions of groups VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide array of group VII is not used with the polynucleotide array of group VIII. Furthermore, these inventions have different modes of operation (require different reagents) and have different functions (detecting polynucleotides or expression of polynucleotides vs. detecting polypeptides or expression of polypeptides).

The inventions of groups VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide array of group VII can be used to detect differential expression of many different proteins and is not capable of use with the method of treating of group IX.

The inventions of groups VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of treating comprising administering an antibody or a polypeptide has different modes of operation, different effects and requires different reagents from the polynucleotide array of group VIII, and further, these inventions are not capable of use together.

3. Upon election of a group outlined above, applicant is further required to elect a single, patentably distinct nucleic acid or polypeptide. This is NOT an election of species. Nucleotide sequences encoding different proteins (see table 2 in the specification) are structurally distinct chemical compounds and are unrelated to one another. These sequences as well as the proteins they encode are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141.

By statute, “[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.” 35 U.S.C. 121. Pursuant to this statute, the rules provide that “[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted.” 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for the remaining groups, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196. The fax phone number for this Group is (703) 305-3014.

Jehanne Souaya  
Patent examiner

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*Jehanne Souaya*  
*6/3/02*